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UNCLAS SECTION 01 OF 05 BRASILIA 003122

SIPDIS

SENSITIVE

STATE FOR EB/TPP/MTA/IPC SWILSON

STATE PASS TO USTR FOR SCRONIN

USDOC FOR 4322/ITA/IEP/WH/OLAC-SC

USDOC ALSO FOR 3134/ITA/USCS/OIO/WH/RD/CREATORE

NCS FOR JOANNA WALLACE

AID FOR CAROL DABBS, LAC/RSD

AID ALSO FOR PAUL DELAY, G/PHN/HN/HIV/AIDS

E.O. 12958: N/A
TAGS: KIPR ETRD PGOV ECON EINV SOCI BR
SUBJECT: NEW DECREE TO FACILITATE IMPORTATION OF COPIED DRUGS THROUGH COMPULSORY LICENSING

REF: SAO PAULO 1467

¶1. (U) SUMMARY: The GoB has taken its latest step in laying the legal groundwork necessary to import copied versions of patented pharmaceuticals. President Lula signed a decree on September 4 revising the implementation of Article 71 of Brazil's 1996 patent law, which governs the granting of compulsory licenses in cases of national emergency or public interest. This decree ratchets up the Ministry of Health's bargaining power in its continuing negotiations with three drug companies over the prices of their AIDS antiretroviral medicines (reftel). The decree quickly followed the conclusion of the WTO agreement on access to medicines. While it is unclear whether the revisions to Article 71 implementation legislation are TRIPS-compliant or even consistent with Brazil's own Constitution, the GoB believes it now has considerably more room to maneuver in cases of public urgency. The decree and the Health Ministry's dwindling stocks of the drugs in question indicate to us that the GoB is prepared to issue compulsory licenses and import if price negotiations are not concluded to its satisfaction. Translated text of the decree from the State Department Translation Service is provided below (paragraph 16). END SUMMARY.

The Revisions and What They Mean

¶2. (U) The most significant revision, in Article 10 of the decree, allows for the importation of the object of the compulsory license when it is not possible to address national emergency or public interest situations with a product on the domestic market, or when production by the State or a third party is not feasible. The previous language of Article 10 allowed for this circumstance "provided that the product has been placed on the market directly by the owner or by consent of the owner," implying that consent by the patent owner was necessary before such (presumably parallel) importation could occur. The replacement language of the new decree does not specify that any action by the patent holder is required. Pharmaceutical companies interpret this fact as giving the green light for imports without the patent holder's consent, permitting entry of knock-offs from countries where there is no patent.

¶3. (U) An additional paragraph under Article 10 states that the Union is obliged to acquire the product placed on the market by the owner or with the owner's consent (e.g. parallel imports), as long as that procedure does not frustrate the purposes of the license. In essence, it would seem that the State can now choose the desired product source by merely alleging the patent owner is thwarting the purpose of the compulsory license, e.g., by not lowering prices.

¶4. (U) The new decree also deletes language in the previous version regarding the public bid process that was to govern the contracting of third parties to work compulsory licenses. The public bid procedures outlined in a 1993 law are no longer to apply. A new paragraph states that patents under compulsory license shall be worked by third parties in compliance with the principles of Article 37 of the Constitution and other applicable legal standards. Article 37 of the Constitution deals with public administration in general, and would impose more relaxed standards on the public bid process than those outlined in the 1993 law.

¶5. (U) Revisions of Article 5 clarify that the patent holder may be obliged to provide sufficient information to enable the reproduction of the object of the compulsory license. The significant alteration in this article under the new decree is

the threat of nullification of the patent should the transfer of know-how not be forthcoming.

¶6. (SBU) The Ministry of Health, in its announcement of the decree, characterized the measure as a legal instrument by which the Brazilian government can import copies in cases of national emergency or public interest without the necessity of the patent holder's consent. In particular, the decree would allow importation of copies of the three AIDS anti-retrovirals that are currently the subject of price negotiations, should the government pursue compulsory licenses. While MoH officials from the International Affairs office declined to comment on the ongoing negotiations with the three pharmaceutical companies (reftel) in a September 4 meeting with Econoffs, they portrayed the issue as a question of life and death for AIDS patients and thus also a political requirement for the GoB.

¶7. (U) Although the MoH's budget allocation decisions did not enter into the conversation with Econoffs, press accounts of the negotiations with pharmaceutical firms typically cite the Ministry's overburdened budget. While seeking to lower costs of medicines in its AIDS program, the Ministry reportedly plans to increase spending on state-run pharmaceutical production facilities. Local press reports of September 1 highlighted Health Minister Costa's announcement that 36 million reais (approximately $12.4 million USD) from the Ministry's 2003 budget, formerly sequestered, are finally to be released to finance capacity building at state-owned laboratories. The 2004 budget draft increases that amount to 80 million reais.

Industry Concern Deepens with New Decree in Place

¶8. (SBU) In a September 19 telcon with Embassy Econoff, Merck Communications Director Joao Sanches expressed his concern over what he characterized as growing anti-patent sentiment in Brazil. He said the recent decree and several bills currently before Congress all seek to limit patent holder rights. Citing assessments of the decree from Brazilian intellectual property lawyers, Sanches said that its constitutionality is questionable, as federal government actions are not supposed to impose additional requirements beyond the limits set by the law. More optimistically, he stated that lower-level MoH contacts have told him the GoB does not want to employ the new decree, preferring a negotiated solution to the imposition of compulsory licensing.

¶9. (SBU) In a separate September 19 meeting with Sao Paulo econoff, FCS principal commercial officer and Brazilian Research-based Pharmaceutical Manufacturers' Association (Interfarma) President Flavio Vormittag, Sanches expanded on the above concerns, highlighting what he characterized as the MoH's lack of response to industry overtures in the area of price reductions and the absence of open dialogue between the companies and the MoH during the negotiation process. According to Sanches, recent proposals by both Abbott and Roche were again refused by the MoH as unsatisfactory. (Note: Sanches was disillusioned that the MoH has at no time during current negotiations recognized the significant price reductions the companies instituted over the past few years in support of Brazil's AIDS program. Only two years ago, Merck received plaudits in the press and from the former head of Brazil's National AIDS program for the price cuts they delivered. Roche also cut its price for Nelfinavir in almost half that same year. End note.) Sanches revealed that Merck had formally requested a 60-day extension (beyond the original August 31 deadline) from the MoH negotiating team so as to review the price reduction demands for Efavirenz in the context of Merck's global pricing policy. Sanches emphasized that any changes to pricing levels in the Brazilian market would require buy-in from Merck's executive body. The MoH had not formally responded to the extension request, but Sanches believed the MoH intended to send a formal communique this week in essence denying their appeal for an extended negotiating timeline. Sanches further stated that Merck's formal requests for a meeting with Minister Costa have gone unanswered. According to Sanches, Costa has yet to receive representatives from any of the three companies since negotiations began.

¶10. (SBU) Sanches reiterated Merck's position that the prices demanded by the MoH are below cost and even lower than those Merck has granted to least-developed countries in Africa. He stated that they amount to a 45 percent reduction for Merck and an 84 percent reduction for Abbott (reftel). Sanches mentioned that Merck has a contract with the GOB valid through the end of this year. Despite the hard stance taken by the GoB, Sanches did not seem to think that the GoB would risk breaking the pricing contracts at this time and still sees some hope for negotiation on the pricing issue. (Note: Sanches also stated that the price currently demanded by the GoB is lower even than that which can be obtained through importation of the drugs from India or China, and suggested that this supports the view that the GoB would prefer a negotiated solution to employing the new decree. End note.)

¶11. (SBU) While the GoB claims its revisions to Article 71

implementation legislation are TRIPS-compliant, both Sanches and Vormittag disagree. Interfarma has contracted a team of lawyers to review the two documents to determine whether or not the GoB would be violating TRIPS through the issuance of a compulsory license under the new decree.

¶12. (SBU) Both Vormittag and Sanches predicted that if a compulsory license were issued for anti-retrovirals, the GoB might decide to expand such action to other medications (i.e. vaccines, cancer, malaria, and tuberculosis), and even to other sectors (e.g. software). They were fast to point out that the decree is not AIDS-drug-specific. Vormittag opined that the GoB started with anti-retrovirals because AIDS is a high-profile issue, backed by a well-organized group in Brazil; universal access to medication for all AIDS patients is also written into Brazilian law, providing a more formidable basis for issuing compulsory licenses in the name of the public interest.

Merck Contemplates Its Options

¶13. (SBU) Sanches admitted that at this time the least painful road for Merck to take would be to negotiate a smaller price reduction or agree to voluntary licensing. Merck is currently working with a team from Fiocruz to analyze the technical requirements for manufacturing under a voluntary license. The company has yet to make a final decision. (Note: This is a change in stance from previous conversations with Sanches in that he now believes the MoH may accept one or the other demand, no longer obliging the patent-owners to comply with both requirements -- price reduction and voluntary licensing -- included in the original MoH Administrative Rule governing the negotiations. End note.)

Meanwhile, More Social-Policy Pressure

¶14. (U) The first National Conference on Medicines and Pharmaceutical Assistance took place in Brasilia September 15-18, ending with consensus that the country needs to guarantee public access to free, quality pharmaceuticals. The Minister of Health opened the conference, which brought together academics, bureaucrats and business representatives to propose recommendations to be incorporated in the Ministry's pharmaceutical policy. One of the conference resolutions suggested revision of Brazil's patent law to allow for local production or importation of expensive medicines in cases of "relevant social interest."

Comment

¶15. (SBU) While we cannot guess at the outcome of the current price negotiations, we do judge that the GoB will not let Brazilian HIV/AIDS patients go without these vital medicines, nor will it be willing to divert significant additional budgetary resources to meet increasing demand for the latest generation of drugs. The global adulation of the GoB's AIDS program, plus the emergency status that the WTO has conferred upon the AIDS epidemic, make it likely that the GoB will employ compulsory licensing to assure the supply of AIDS drugs unless the desired price reductions are negotiated. Importation of knock-offs would likely be a temporary measure until the state-owned lab can begin internal production. Whether Brazil can actually startup production of these pharmaceuticals as cheaply as Brazilian officials seemingly assume is not a foregone conclusion. END COMMENT.

Text of Decree

¶16. (U) Decree No. 4,830 of September 4, 2003

Redrafting Articles 1, 2, 5, 9, and 10 of Decree No. 3,201 of October 6, 1999, which provides for automatic issuance of compulsory licenses in national emergencies or when in the public interest, as defined in Article 71, Law No. 9,279 of May 14, 1996.

The President of the Republic, by virtue of the authority conferred by Article 84(IV) of the Constitution, and under the provisions of Article 5(XXV) and (XXIX), and Article 71 of Law No. 9,279 of May 14, 1996, Hereby Decrees:

Article 1. Articles 1, 2, 5, 9, and 10 of Decree No. 3,201 of October 6, 1999, enter into force with the following wording:

"Article 1. Automatic issuance of compulsory licenses during national emergencies or when in the public interest, and in the latter case only for non-commercial public use as defined in Article 71, Law No. 9,279 of May 14, 1996, shall take place as stipulated in this Decree." (NR)

"Article 2. A compulsory patent license may be issued automatically when the State declares a national emergency

or when in the public interest, and in the latter case only for non-commercial public use, when it is determined that the patent owner is not addressing those needs either directly or through a licensee." (NR)
"Article 5. Issuance of the compulsory license shall establish the following conditions, among others:
I - The period of validity of the license and the possibility of extending it; and
II - The conditions imposed by the State, particularly with regard to reimbursement of the patent owner.
¶1. Issuance of the compulsory license may also include a requirement for the patent owner to furnish enough information to effectively reproduce the object of protection and other technical aspects applicable to the specific case; the provisions of Article 24 and of Title I, Chapter VI, of Law No. 9,279 of 1996 shall apply should such information not be forthcoming.
¶2. In calculating appropriate compensation for the patent owner, relevant economic and market circumstances shall be taken into account, as shall the prices of similar products and the economic value of the authorization."
"Article 9. Patents licensed according to this Decree may be worked directly by the State or by third parties under contract or agreement, and the object of the patent for any other purpose may not be reproduced under penalty of being deemed illegal.
Single paragraph. Patents under compulsory license shall be worked by third parties in compliance with the principles of Article 37 of the Constitution and other applicable legal standards."
"Article 10. When it is impossible to address national emergency or public interest situations with a product on the domestic market, or when production of the patented article by third parties or by the State is not feasible, the patented product may be imported.
"Single paragraph. For cases foreseen in the main body of this Article, the State shall be given preference in the acquisition of the product placed on the market directly by the owner or by consent of the owner, as long as that procedure does not thwart the purposes of the license."
(NR)
"Article 2. This Decree shall enter into force on the date of its publication."
"Article 3. Article 11, Decree No. 3,201 of October 6, 1999, is hereby revoked."
Brasilia, September 4, 2003.
Luiz Incio Lula da Silva
Humberto Sergio Costa Lima
Luiz Fernando Furlan

This text does not replace the text published in the Official Gazette on 9/5/2003
End Text.

¶17. This cable was coordinated with AmConsulate Sao Paulo.

VIRDEN